K090636

510(k) Summary

DEC - 2 2009

Applicant's Name and Address

TSO_3 Inc.
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Canada G1P 3S5

Contact Person, Telephone, FAX

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U.S. Agent

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Submission Date

March 4, 2009

Trade Name

TSO_3 STERIZONE® *125L* Sterilizer

Common Name

TSO_3 *125L* Ozone Sterilizer

Classification Name

Sterilizer, Chemical

Class II (as per 21CFR, part 880.6860 equivalent device)

Legally Marketed Equivalent Device Name(s)

TSO_3 Ozone Sterilizer, model *125L* (K020875) (K051595)

Description of Device

TSO_3 Ozone Sterilizer, model *125L* is intended to sterilize medical devices that has been previously cleaned.

The sterilization chamber has a capacity of 125 liters (4.3 cu. ft.).

It requires USP grade oxygen, water and electricity. TSO_3 Sterilizer could be installed as a free standing unit or recessed behind the wall. No exhaust gas ventilation duct is required as long as the room is adequately ventilated. By-products are oxygen and low humidity water vapor.

Model *125L* is equipped with a unique factory-programmed control system.

Non-woven wrapping material or pouches and anodized aluminum containers are used as packaging for medical devices to be sterilized.

OZO-TEST® self-contained Biological Indicators *(B. stearothermophilus)* are recommended for use in evaluating cycle performance.

TSO_3 Chemical Indicators are available for this process.

No aeration is needed following the sterilization cycle. The sterilized items are cool to the touch and can be removed immediately and used, or stored for future use.

Effectiveness

Ozone Sterilizer validation testing for sterilization of flexible endoscopes was performed using the « overkill » approach to demonstrate the effectiveness of the process.

The effectiveness of the ozone sterilization process in sterilization of flexible endoscopes is demonstrated by the full cycle validation testing in simulated use conditions, half-cycle validation testing and in-use testing.

Safety

Safety of the TSO_3 Ozone Sterilizer, model *125L* was demonstrated into the original 510(k) submission (K020875). The content of the actual submittal does not compromise the safety of the device.

The safety of the ozone sterilization process in sterilization of flexible endoscopes is demonstrated by the processed device/material qualification testing which includes material effects, functional compatibility and biocompatibility evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

TSO3 Incorporated
C/O Mr. Charles O. Hancock
Regulatory Affairs Consultant
Charles O. Hancock Associates, Incorporated
33 Black Watch Trail
Fairport, New York 14450

DEC - 2 2009

Re: K090636
Trade/Device Name: TSO_3 Ozone Sterilizer, Model 125L
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: FLF
Dated: November 12, 2009
Received: November 12, 2009

Dear Mr. Hancock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090636

Device Name: **TSO_3 Ozone Sterilizer, model *125L***

Indications for Use:

TSO_3 *125L* Ozone Sterilizer is intended for use in the sterilization processing of reusable medical devices in health care facilities. TSO_3 *125L* Ozone Sterilizer is designed for sterilization of both metal and non-metal medical devices at low temperatures.

TSO_3 *125L* Ozone Sterilizer has the ability to sterilize successfully packaged rigid and flexible lumen medical devices, including single and multi channel flexible endoscopes such as fiberoptic and video endoscopes.

Notes:

- Testing on flexible endoscopes was conducted employing half cycle to demonstrate achievement of a sterility assurance level (SAL) of 10^{-6}.
- During the sterilization cycle, items are exposed to ozone at a concentration of 85 milligrams per liter for 15 minutes at a temperature of 30.8°C to 36.1°C (87.4°F to 97°F).
- Sterilization efficacy was demonstrated for a load comprising packaged multi channel (2) and single channel (1) flexible endoscopes having a total of 14 channels in the presence of other packaged medical devices. The load configuration used for qualification testing contained 2 multi channel and one single channel flexible endoscope, plus 14 medical devices packaged in TSO_3 Sterilization Pouches and a Process Challenge Device. Total weight of the load was 49 lbs.
- For the purpose of this submission:
  - Single channel flexible endoscopes refer to medical devices having only one channel.
  - Multi channel flexible endoscopes refer to medical devices that may have two or more channels such as: Working channel (biopsy); Water jet; Air feeding; Water feeding; Suction;
- Endoscopes evaluated include: Colonoscope, Gastroscope, Broncho videoscope, Choledofiberscope and Ureteroscope.

Prescription Use _____ AND/OR Over-The-Counter Use __X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie-Wilson
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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